Molluscan Shellfish Institute

a division of National Fisheries Institute

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98P-0504, Performance Standard for *Vibrio vulnificus*

Dear Sirs or Mesdames:

This letter responds to the Food and Drug Administration's request for comments on a performance standard of nondetectable for *Vibrio vulnificus*. The Molluscan Shellfish Institute believes the petition submitted by the Center for Science in the Public Interest, which requests this nondetectable performance standard should be rejected for the following reasons: Vibrio vulnificus is a naturally-occurring organism in marine environments; it is not ordinarily injurious to humans; the post harvest treatments necessary to reach nondetectable levels result in a product different from a live raw oyster, thus, reduce consumer choice; insufficient scientific data is available to evaluate the safety and efficacy of the treatments; the cost of the treatments and impacts on the existing market for live shellfish could have serious adverse effects on the industry; and establishment of a performance standard by FDA would circumvent the system of determining effective shellfish sanitation controls through the Interstate Shellfish Sanitation Conference.

By way of brief background, the Molluscan Shellfish Institute (MSI) is one of the oldest trade associations representing the shellfish industry. Its members pack, process and distribute oysters, clams and mussels. MSI has been an active participant in the Interstate Shellfish Sanitation Conference since its inception and continues to support the ISSC as appropriate forum to establish shellfish control procedures and standards.

The FDA Notice indicates that the Center for Science in the Public Interest (CSPI) petitioned the agency to establish a nondetectable performance standard for *Vibrio vulnificus* in shellfish harvested from waters linked to illness. The MSI has held meetings with other shellfish industry organizations and sought input from its members regarding the CSPI petition and the questions contained in the FDA Notice. The purpose of these comments is to: recommend that FDA deny the CSPI petition for the reasons stated above, and answer the eight questions raised in the Notice.

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Our answers to the questions are organized and presented consistent with the format of the FDA Notice.

1. Is the AmeriPure Co. technology readily employable, if not, what are the barriers?

   "Employability" necessitates that the product resulting from this post-harvest treatment be marketable. At best, it can be said that consumer acceptability of treated oysters in the existing live shellfish market is unproven. Reportedly, some buyers have tried the treated oysters and reverted back to the live product. MSI supports the advancement and voluntary use of this and other emerging post-harvest treatments but does not believe mandating them for shellfish products is justified or necessary.

   Barriers to its employability include:

- The resulting product is not a live shellfish, hence, consumer marketability is expected to be limited;

- Treated oysters, reportedly, have inconsistent color and texture;

- Difficulties are anticipated in ensuring the necessary refrigeration requirements (i.e. 38 degrees F) throughout all distribution and marketing levels;

- Patent and licensing requirements for the technology present unknown complications;

- The cost of the process, including equipment, handling, and franchising is not precisely known but is believed to be high; and

- Consumers might be confused by the differences between the live and treated products, which could lead to mishandling problems.

2. What technologies, other than AmeriPure, could significantly reduce *V. vulnificus* and retain the sensory characteristics of raw oysters? What is known about the ability of these technologies to reach nondetectable *V. vulnificus*?

   All the post-harvest technologies currently under study kill the animal, with the exception of irradiation, thereby, changing the inherent condition of the product. Irradiation results in nondetectable levels without killing the live animal but is not approved by FDA. Freezing with liquid carbon dioxide results, reportedly, in levels approaching nondetectable. High pressure shows promise but is still in the experimental stage. Depuration and relaying in high salinity water can not guarantee nondetectable levels.

3. How reliable are the technologies? May they be practically required for all or part of the shellfish industry?

The reliability of the technologies is not fully known owing to their limited use in commercial processing operations. Some technologies hold promise for lowering levels of *V. vulnificus* but result in products that are different than the live raw products. Specialized handling and storage requirements present problems that must be overcome.

Moreover, it is impractical and unjustifiable to mandate a particular treatment for all shellfish. The use of the technologies should be at the discretion of the industry.

4. Is a performance standard other than nondetectable permissible?

   A performance standard, at any level, is not appropriate for oysters or other molluscan shellfish because *V. vulnificus* is a natural inhabitant of the estuarine environment and is not ordinarily injurious. A specific link between the organism and illness has not been established.

5. Should a performance standard apply to all raw molluscan shellfish?

   A performance standard is not appropriate for oysters or other molluscan shellfish. It would be especially inappropriate and illogical to establish a standard for species and products to which illnesses have never been attributed.

6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, if there were one patented treatment to meet the standard?

   If a performance standard were enacted that eliminated raw, live oysters/shellfish from the marketplace, there would be a non-quantifiable socio-economic and cultural loss to consumers. People have enjoyed oysters in various forms, including live since ancient times. A performance standard would likely eliminate live, raw oysters as a consumer choice. Financial costs to processors, harvesters, distributors, retailers, foodservice operators and consumers would be substantial. It is difficult to quantify this cost since many variables need evaluation. Major cost factors include the marketability of post-harvest treated products, the cost of the treatment process, and the cost associated with attaining lower temperature requirements, when necessary.

   The ISSC plans to undertake a study to evaluate market impacts and implementation costs associated with performance standards. It would be prudent to examine the results of the study before further assessment of economic impacts is weighed.

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy these?

The benefit of a performance standard would pertain to a small group of vulnerable individuals (i.e. a subset of the total at-risk population) who would be able to consume post- harvest treated product with reduced risk of illness. This group ranges from 15 to 20 individuals per year out of a total at-risk population of 30 million.

8. Should a performance standard apply only to *V. vulnificus* or include *V. parahaemolyticus?*

There should be no performance standard established for either bacterium. If the agency chooses to pursue this procedure for establishing a performance standard as a result of the petition, it clearly should not include *V. parahaemolyticus*, since the petition does not include this organism.

The agency has a respectable record of working through issues in cooperation with the ISSC. It would be appropriate for FDA to refer the issue to that body for its consideration according to established procedures rather than take unilateral action on it.

In closing, the MSI believes there is inadequate justification for establishing a performance standard of nondectable for *Vibrio vulnificus* in oysters and other molluscan shellfish. Moreover, the issues raised in the CSPI petition should be discussed, evaluated and addressed through the established process available through the ISSC. Thank you for your consideration of our comments.

Sincerely,

Robert L Collette

Robert L. Collette
Director